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NOTICE OF ALLOWANCE AND FEE(S) DUE

25291 759n WYETH LLC PATENT LAW GROUP

05/14/2010

EXAMINER SHEIKH, HUMERA N

PAPER NUMBER

ARTINE 1615 DATE MAILED: 05/14/2010

5 GIRALDA FARMS MADISON, NJ 07940

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.			
10/643,623	08/19/2003	Janos Szamosi	AM100224 P1	4463			
TITLE OF INVENTION: FAST DISSOLVING TABLET							

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/16/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED.</u> THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown

B. If the status above is to be removed, check box 5b on Part B -Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This appropriate. All further indicated unless correcte maintenance fee notificat	form should be used to correspondence including d below or directed off tions	for transmitting the ISS ig the Patent, advance of nerwise in Block 1, by	UE FEE and PUBLICATI orders and notification of r (a) specifying a new corres	ON FEE (if require naintenance fees will pondence address; a	 d). Blocks 1 through 5 : be mailed to the current nd/or (b) indicating a sep 	should be completed where t correspondence address as arate "FEE ADDRESS" for	
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block I for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
25291 WYETH LLC PATENT LAW 5 GIRALDA FA	RMS	V2010	I be	Certify	icate of Mailing or Trans Fee(s) Transmittal is bein	smission g deposited with the United st class mail in an envelope above, or being facsimile date indicated below.	
MADISON, NJ	07940					(Depositor's name)	
						(Signature)	
						(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	Α	TTORNEY DOCKET NO.	CONFIRMATION NO.	
10/643,623	08/19/2003	•	Janos Szamosi		AM100224 PI	4463	
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nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/16/2010	
EXAM	INER	ART UNIT	CLASS-SUBCLASS]			
SHEIKH, H		1615	424-464000	•			
"Fee Address" indi PTO/SB/47; Rev 03-0 Number is required.	ondence address (or Cha 3/122) attached. ication (or "Fee Address' 2 or more recent) attach	inge of Correspondence "Indication form acd. Use of a Customer	2. For printing on the p (1) the names of up to or agents OR, alternativ (2) the name of a single registered attorney or a 2 registered patent atto listed, no name will be	3 registered patent a vely, e firm (having as a m agent) and the names meys or agents. If no printed.	somber a 2		
	ess an assignee is ident h in 37 CFR 3.11. Comp GNEE	ified below, no assigned pletion of this form is NO	(B) RESIDENCE: (CITY	atent. If an assignee assignment. and STATE OR CO	UNTRY)	occument has been filed for	
4a. The following fee(s) a	are submitted:	4	lb. Payment of Fee(s): (Plea ☐ A check is enclosed. ☐ Payment by credit car	d. Form PTO-2038 is	previously paid issue fee s attached. the required fee(s), any d	shown above)	
	s SMALL ENTITY state	as. See 37 CFR 1.27.	☐ b. Applicant is no lon	ger claiming SMALL	ENTITY status. Sec 37 C	FR 1.27(g)(2).	
interest as shown by the r	ecords of the United Sta	tes Patent and Trademar	eu irom anyone otner than t k Office.	ne appucant; a registe	acu auorney or agent; or t	he assignee or other party in	
Authorized Signature				Date			
Typed or printed name				Registration No.			
This collection of inform an application. Confident submitting the completed this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C itality is governed by 35 I application form to the ons for reducing this but irginia 22313-1450. DC 13-1450.	EFR 1.311. The informat U.S.C. 122 and 37 CFR USPTO. Time will var rden, should be sent to to D NOT SEND FEES OR	ion is required to obtain or r k 1.14. This collection is est y depending upon the indiv he Chief Information Office COMPLETED FORMS TO	etain a benefit by the imated to take 12 min idual case. Any comer, U.S. Patent and Tr D THIS ADDRESS.	public which is to file (an nutes to complete, includi ments on the amount of ti ademark Office, U.S. Dep SEND TO: Commissioner	d by the USPTO to process) ng gathering, preparing, and me you require to complete sartment of Commerce, P.O. for Patents, P.O. Box 1450,	

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APPLICATION N	О.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,623	08/19/2003		Janos Szamosi	AM100224 P1 4463	
25291	7590	05/14/2010		EXAMINER	
WYETH LLC			SHEIKH, HUMERA N		
	PATENT LAW GROUP			ART UNIT	PAPER NUMBER
5 GIRALDA FARMS MADISON, NJ 07940			1615 DATE MAII ED: 05/14/201	0	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 518 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 518 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/643 623 SZAMOSI ET AL. Notice of Allowability Examiner Art Unit Humera N. Sheikh 1615 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to paper filed 21 April 2010. 2. The allowed claim(s) is/are 38 and 40. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) \(\subseteq \text{Some* c} \) \(\subseteq \text{None of the:} \) a) \square All 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3.
☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6.

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date 3. Information Disclosure Statements (PTO/SB/08), 7.

Examiner's Amendment/Comment Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material Other . /Humera N. Sheikh/ Primary Examiner, Art Unit 1615

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-06) Notice of Allowability Part of Paper No./Mail Date 20100510 Art Unit: 1615

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Final Office Action and Applicant's Arguments filed 04/21/10 is acknowledged. The Amendment has been entered.

Claims 38 and 40 are pending in this action.

Allowable Subject Matter

Claims 38 and 40 are allowed.

The following is an examiner's statement of reasons for allowance: The primary reasons for allowance are that the prior art of record (Shimizu et al. - U.S. Pat. No. 6,299,904) does not disclose nor teach or fairly suggest a tablet consisting of the specific combination of ingredients as presently claimed whereby the tablet has a hardness of less than 1.5 kP. Shimizu does not teach the combination of a single saccharide and a low melting point compound to form a fast-dissolving granulation.

The instant invention demonstrates an improvement over prior art compositions, in that it provides for fast-dissolving tablets having low hardness and good physical stability whereby the tablets can be made using very low compression force and yet have acceptable stability.

In the Response filed 04/21/10, Applicant has overcome the claim objections (to claims 33 and 37), the 35 U.S.C. §112, first paragraph rejection (of claim 32) and the 35 U.S.C. §103(a) obviousness rejection (of claims 32 and 34-36) based on the cancellation of these claims. Accordingly, the instant invention is rendered novel and patentable over the prior art of record.

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Any comments considered necessary by applicant must be submitted no later than the

payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for

Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the

organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

 $system, see \underline{\ http://pair-direct.uspto.gov}. \ \ Should \ you \ have \ any \ questions \ on \ access \ to \ the \ Private$

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

May 10, 2010

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